COVID-19 Response: Safety for ROP Screening in Neonatal Intensive Care Unit

Candice D. Frazier

Abstract:

Background: This publication demonstrates how utilizing a telemedicine-based evaluation for Retinopathy of Prematurity is a secure and safe solution for screening during the global COVID-19 pandemic. The purpose of this publication is to provide current users and potential users with an understanding of how telemedicine-based evaluations can minimize potential outside exposure risks induced by bedside binocular indirect ophthalmoscopy examinations.

Methods: The publication compares the current workflow of bedside binocular indirect ophthalmoscopy exams and their potential to outside exposures to telemedicine-led screening programs housed in the hospital facility. Also discussed are the methods for high-level disinfecting medical devices and the importance of these protocols in the current pandemic state.

Findings: Results reveal that experts tend to support discussions surrounding telemedicine's accuracy and reading images for the diagnosis and monitoring of Retinopathy of Prematurity.

Discussion: Telemedicine based evaluations with ultra-widefield imaging devices allows hospital organizations to control their screening process in-house, with crucial high-level disinfection procedures in place.

Implications for Practice: The publication will be educational to neonatal intensive care staff members for creating best practices in screening for Retinopathy of Prematurity to protect patients from unnecessary virus exposure.

Implications for Research: The research in this publication discusses the overall support of a telemedicine approach for screening of Retinopathy of Prematurity. More research is needed to update specific guidelines and policy statements to promote this workflow through neonatal intensive care units.

Keywords: COVID-19, Retinopathy of Prematurity, Ultra-wide Field Imaging, Telemedicine

Understanding what we know about COVID-19

COVID-19 was officially named by the World Health Organization (WHO) on February 11, 2020. The abbreviation COVID-19 is noted to mean CO for 'corona,' VI for 'virus,' D for 'disease,' and the year 2019. The new, or novel, coronavirus is a new disease that had not been seen in humans until recently. COVID-19 is believed to spread in ways similar to the common cold—such as through coughs, sneezes, or handshakes. A person who has caught the virus may not show symptoms for between 5-14 days. This interval is called the incubation period. The person can spread the virus during this time. (1)

Although the transmission to a person from surfaces that have been potentially contaminated is still not well documented, there are immediate concerns regarding the need to follow stringent disinfection measures on all surfaces and medical devices. The CDC has raised concerns that the virus may live on non-disinfected surfaces for up to 9 days. More studies have shown that the novel coronavirus is likely spread through respiratory droplets. It is possible that by touching an infected surface or persons, the virus can then be spread if one touches their own mouth, nose, and eyes. (2)

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The first concerns surrounding COVID-19 were reported to WHO on December 31 of 2019.(3) These initial findings are thought to be discovered by a practicing ophthalmologist showing concern for an increasing number of patients presenting with pneumonia-like symptoms.(4) Since these initial findings, the coronavirus outbreak has significantly impacted local and global health and related economies. It also raises concerns for Ophthalmology and hospital facilities regarding the future of care related to screening for Retinopathy of Prematurity (ROP).

Understanding what is known about Retinopathy of Prematurity

Retinopathy of prematurity is a disease process that affects babies who are born prematurely. ROP remains a significant threat to vision health, especially in extremely premature and underweight infants. According to the National Eye Institute (NEI), between 14,000 and 16,000 infants in the United States are affected with some degree of ROP each year. Each year, 400 to 600 of those infants will become legally blind from ROP. (5)

There are five stages classified in ROP, ranging from mild to severe. Most infants who develop ROP will have mild stages I or II. Those infants who may develop rapidly advancing ROP are at risk for permanent visual loss. (5)

In ROP, abnormal blood vessels can grow and spread through layers of the retina, causing scarring or detaching. Several complex issues may cause ROP. In the stages of development, the retina will begin to vascularize from the optic nerve out into the periphery. When an infant is born prematurely, before the retina has fully vascularized, normal blood vessel growth will be affected. (5)

The relation between ROP and COVID-19 is still being researched. Studies are currently underway to determine how COVID-19 may affect fetal distress and respiratory distress in preterm infants. Increases in stressors and premature birth may lead to increases in risks for infants developing ROP. (6)

Current workflows in ROP screening management

According to the American Academy of Pediatrics, the current workflow for screening for retinopathy of prematurity is supported with bedside binocular indirect ophthalmoscopy performed by an off-site physician. These exams require physicians who specialize in retinal ophthalmology to enter the NICU to perform exams with scleral depression and a high magnification lens, and then confirm ocular findings with a hand-drawn image. The AAP has currently acknowledged the need for support of telemedicine programs and has suggested workflow options to create a successful imaging and telemedicine program.(7)

As we see the COVID-19 pandemic develop, hospital facilities will likely implement procedural changes related to how off-site contract physicians access the premises and patient care areas. Telemedicine for the evaluation of retinopathy of prematurity allows for the off-site ophthalmologist to diagnose and follow ROP diagnosis, avoiding repeated exposure in the NICU environment appropriately and safely

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Studies have been performed to support discussions surrounding telemedicine's accuracy and reading images for the diagnosis and monitoring of ROP. These studies have found that sensitivity of 100% and specificity of 97% when detecting the diagnosis of pre-threshold or worse ROP. Some studies have even found that ultra-widefield imaging can capture photo documentation of mild ROP in cases ophthalmoscopy may have missed. (8)

The role of ultra-widefield imaging to improve patient care, especially in times of pandemic and disease control

Ultra-wide field imaging (RetCam® 3, RetCam Shuttle, or RetCam Portable; Natus Medical Incorporated, Pleasanton, CA) facilities create a permanent, still or video, digital image of the retina, cornea, and/or external structures of the eye. The original images cannot be altered. A digital image is not subject to the predictable inaccuracies associated with the current practice of viewing a structure and subsequently making handwritten notes and/or paper sketches or drawings in an attempt to record what was seen. (9)

Digital images are readily available for direct comparisons over time. As the images are captured at various intervals, they can be displayed side-by-side on a screen, allowing the physician to track disease progression and determine the need for any intervention. These permanent images can become a part of the patient's medical record. (9)

Telemedicine and ultra-widefield imaging can help hospitals and NICU's facilitate well-coordinated ROP programs and limit not only outside exposure to infants and parents but also NICU staff, physicians, and patients throughout the hospital. These solutions provide continuity of care and offer a high level of expertise to each child evaluated.

Along with protection provided to hospital staff and patients, these telemedicine solutions protect off-site physicians from having to enter a hospital facility. While ophthalmologists may have heavy clinic flows in their practices, the addition of remote viewing allows them to review images quickly and in the comfort of their office. Ultra-wide field imaging allows for closer scrutiny of diagnosis and treatment, along with the ability to request second opinions when needed.

Understanding the importance of device reprocessing to minimize possible exposure

It is important to understand the importance of disinfection and reprocessing of reusable medical devices. With the onset of COVID-19 and the potential for future exposure to these viruses, the need for medical devices with thorough reprocessing instructions will be an immediate requirement for hospital facilities worldwide.

According to the Food and Drug Administration (FDA), when reusable medical devices are put into service on patients, the devices can become soiled and contaminated with microorganisms. Any reusable medical device must undergo what is known as reprocessing to minimize the risk of spreading infection by a contaminated device. The FDA defines reprocessing as "a detailed, multistep process to clean and then disinfect or sterilize" medical devices. (10)

As related to the COVID-19 response, the risks involved with exposure are directly related to the virus's transmission through respiratory droplets spread from person or surface to another. This is a direct concern in the instance of Retinopathy of Prematurity exams that involve touching areas around the eyes and the nose and mouth of small infants who may have compromised immune systems.

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Both the FDA and many medical device manufacturers can agree that adequate reprocessing of reusable medical devices is vital to protecting patient safety. Taking steps to review and advance current reprocessing protocols will help protect patients in the immediate need and the future. (10)

Summary of Recommendations for Practice and Research

What we know:

- COVID-19 is believed to spread in ways similar to the common cold—such as through coughs, sneezes, or handshakes.
- It is possible that by touching an infected surface or persons, the virus can then be spread if one touches their mouth, nose, and eyes.
- According to the National Eye Institute (NEI), between 14,000 and 16,000 infants in the United States are affected with some degree of ROP each year.
- According to the American Academy of Pediatrics, the current workflow for screening for retinopathy of prematurity is supported with bedside binocular indirect ophthalmoscopy performed by an off-site physician.

What needs to be studied?

- Procedural changes are related to how off-site contract physicians access the premises and patient care areas.
- Accuracy of telemedicine and reading images for the diagnosis and monitoring of ROP should be reviewed.

What we can do today:

- Telemedicine for the evaluation of retinopathy of prematurity allows for the off-site ophthalmologist to appropriately and safely diagnose and follow ROP diagnosis, avoiding repeated exposure in the NICU environment
- New policies can go into place to address the adherence of best internal practices from an infection control standpoint and minimize exposure from outside contact.
- An ultra-widefield imaging device's placement can eliminate the transmission of disease or bacteria from an exposed off-site ophthalmologist to the NICU patients and staff. This option also decreases the exposure risks for those ophthalmologists who may be entering hospital facilities frequently.

The role of reprocessing in screening for Retinopathy of Prematurity

When considering the need for reprocessing related to screening for Retinopathy of Prematurity, it is important to understand the medical instruments and medical devices used.

Lid Speculums: a lid speculum is a medical instrument used that is used to retract the eyelids. In the case of ROP screening, a speculum is used to hold the lids open during the retina examination. Speculums are typically made of stainless steel and should be autoclaved. Once lid speculums are properly sterilized, they should be packaged for single patient use. Disposable lid speculum packages should be checked for any damage and only used for a single patient. Care should be taken to review all medical safety data regarding proper sterilization as directed by the manufacturer and hospital guidelines.

Scleral Depressors: a scleral depressor is a medical instrument used between the globe and the orbit that displaces the retina inward. For ROP screening, a scleral depressor is used to create an elevation by pushing the retina inward during examination allowing physicians to see the far periphery. Scleral depressors are typically made of stainless steel and should be autoclaved. Once scleral depressors are properly sterilized, they should be packaged for single patient use. Disposable scleral depressor packages should be checked for any damage and only used for a single patient. Care should be taken to review all medical safety data regarding proper sterilization as directed by the manufacturer and hospital guidelines.

Ultra-Wide Field Retinal Imaging Devices: a retinal imaging device

is a medical device for photo documentation of the retina and other ocular structures. For ROP screening, a retinal imaging device is used to examine the retina and allows the ophthalmologist to review the documented photos remotely. In the RetCam devices (RetCam 3, RetCam Shuttle, or RetCam Portable; Natus Medical Incorporated, Pleasanton, CA), the detachable lens tip is made of stainless steel and should be disinfected following the up-to-date guidelines. The disinfection of the lens piece should be completed between each patient. The detachable lenses on the RetCam device allow a rotation in lenses for reprocessing. Care should be taken to review all medical safety data regarding proper disinfection as directed by the device manufacturer and hospital guidelines.

The future of Retinopathy of Prematurity care

With the onset of COVID-19, the world has begun to assess the impacts on the healthcare industry. Changes will be implemented worldwide to provide the best possible care while protecting staff and patients' health. New policies will go into place to address the adherence of best internal practices from an infection control standpoint and minimize exposure from outside contact.

As we look over the current processes for screening for Retinopathy of Prematurity, the future may hold a greater, if not complete, telemedicine led program. With the addition of a RetCam ultra-widefield retinal imaging device, hospitals can create permanent, still, or digital video images of the retina, cornea, and external structures. The original images cannot be altered. A digital image is not subject to the predictable inaccuracies associated with the current practice of viewing a structure and subsequently making handwritten notes and/or hand-drawn sketches/drawings in an attempt to record what was observed.

Digital images are readily available for direct comparisons over time. As the images are captured at various intervals, they can be displayed side-by-side on a screen, allowing the physician to track disease progression and determine the need for any intervention. These permanent images can become a part of the patient's medical record.

The placement of an ultra-widefield imaging device can eliminate the transmission of disease or bacteria from an exposed off-site ophthalmologist to the NICU patients and staff. This option also decreases the exposure risks for those ophthalmologists who may be entering hospital facilities frequently. RetCam systems allow for the disinfection of detachable lenses in an effort to minimize exposure risks and slowdowns in the workflow. One lens can be set aside for controlled reprocessing while the previously disinfected lens is used.

References:

1. *"Coronavirus Disease 2019 (COVID-19)." Centers for Disease Control and Prevention, Centers for Disease Control and Prevention, www.cdc.gov/coronavirus/2019-ncov/index.html.*
2. *"COVID-19 May Be Transmitted Through the Eye, Report Finds." AJMC, www.ajmc.com/newsroom/covid19-may-be-transmitted-through-the-eye-report-finds.*
3. *"Coronavirus Disease (COVID-19)." World Health Organization, World Health Organization, www.who.int/emergencies/diseases/novel-coronavirus-2019.*
4. *Ting, Daniel. "The Complexities of COVID-19 in Ophthalmology." The Ophthalmologist, May 13 2020, theophthalmologist.com/subspecialties/the-complexities-of-covid-19-in-ophthalmology.*
5. *"Retinopathy of Prematurity." National Eye Institute, U.S. Department of Health and Human Services, www.nei.nih.gov/learn-about-eye-health/eye-conditions-and-diseases/retinopathy-prematurity.*
6. *"RE: Retinopathy of Prematurity and COVID-19: Is There a Correlation?" CMAJ, July 1 2020, www.cmaj.ca/content/re-retinopathy-prematurity-and-covid-19-there-correlation.*
7. *Fierson, Walter M. "Screening Examination of Premature Infants for Retinopathy of Prematurity." Pediatrics, vol. 142, no. 6, 2018, doi:10.1542/peds.2018-3061.*
8. *Chiang, Michael F, et al. "Detection of Clinically Significant Retinopathy of Prematurity Using Wide-Angle Digital Retinal Photography: a Report by the American Academy of Ophthalmology." Ophthalmology, U.S. National Library of Medicine, June 2012, www.ncbi.nlm.nih.gov/pmc/articles/PMC3637992/.*
9. *Natus Medical Incorporated. (2018) RetCam 3 and RetCam Shuttle User Manual PN 18-000630 Rev. A*
10. *Center for Devices and Radiological Health. "Reprocessing of Reusable Medical Devices." U.S. Food and Drug Administration, FDA, www.fda.gov/medical-devices/products-and-medical-procedures/reprocessing-reusable-medical-devices.*

Candice D. Frazier, CRA, OCT-C, COA is a clinical specialist and advisor for RetCam Pediatric Retinal Imaging at Natus Medical Incorporated. Financial Disclosure: Is a paid employee of Natus Medical Incorporated, the manufacture of RetCam Imaging Devices.

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Corresponding Author

Candice D. Frazier
Pediatric Retinal Imaging Specialist
CRA, OCT-c, COA

PO BOX 548
Ozark, MO 65721
417-894-0479
CFrazier485@gmail.com